PharmaLogic
Take The Lead

10/4/2016

Regional Director
US NRC Region III
2443 Warrenville, Illinois 60532

RE: Amendment request for NRC RAM License 13-26246-01MD

Dear Sirs,

Please add the following pharmacist (ANP) to our RAM:

- Bynum L. Kimmons, RPh

Mr. Kimmons is recognized as an Authorized Nuclear Pharmacist on NRC License 44-30124-01MD, which I have attached. His MI pharmacist license (also attached) is 5302045036.

Should you need any additional information I may be reached at 678.333.5896, or email rvansant.pharmalogic.info

Thank you,

Richard L. Van Sant

Richard L. Van Sant, PharmD
Director of Regulatory Affairs

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

November 18, 2014

Docket No. 03033449
Control No. 584038

License No. 44-30124-01MD

Richard L. Van Sant, Pharm.D.
Director of Regulatory Affairs
PharmaLogic Ltd.
1191 S. Brownell Road, Suite 40
Williston, VT 05495

SUBJECT: PHARMALOGIC LTD., LICENSE RENEWAL, CONTROL NO. 584038

Dear Dr. Van Sant:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify the NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license

   a) when you decide to terminate all activities involving materials authorized under the license; or

   b) if you decide not to acquire or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a) change Radiation Safety Officers;

b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

c) add or change the areas of use, or addresses of use identified in the license application or on the license; or

d) change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 28

cc:
Richard Sucese, R.Ph., Radiation Safety Officer

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 28

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. PharmaLogic Ltd.	In accordance with the application dated May 29, 2014, 3. License number 44-30124-01MD is amended in its entirety to read as follows:
2. 1191 S. Brownell Road, Suite 40 Williston, Vermont 05495	4. Expiration date November 30, 2024
	5. Docket No. 030-33449 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 3 through 83, except as listed below	A. Any, except sealed sources	A. 200 millicuries per radionuclide and 2 curies total
B. Fluorine 18	B. Any	B. 1 curie
C. Gallium 67	C. Any	C. 500 millicuries
D. Strontium 89	D. Any	D. 40 millicuries
E. Yttrium 90	E. Any	E. 500 millicuries
F. Molybdenum 99	F. Any	F. 100 curies
G. Technetium 99m	G. Any	G. 100 curies
H. Indium 111	H. Any	H. 300 millicuries
I. Iodine 123	I. Any	I. 50 millicuries
J. Iodine 131	J. Any	J. 2.5 curies
K. Xenon 133	K. Any	K. 1.5 curies
L. Samarium 153	L. Any	L. 750 millicuries
M. Thallium 201	M. Any	M. 1 curie
N. Any byproduct material permitted by 10 CFR 31.11(a)	N. Prepackaged units for in vitro diagnostic tests	N. 50 millicuries

License Number
44-30124-01MD Duplicate

Docket or Reference Number
030-33449

Amendment No. 28

MATERIALS LICENSE SUPPLEMENTARY SHEET

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
O. Any byproduct material permitted by 10 CFR 35.65(a)	O. Sealed Sources (Bristol-Myers Squibb Medical Imaging, formerly E.I. DuPont Model NES-356; International Isotopes, Inc. Models BM03-57L and BM03-57A; International Isotopes Idaho, Inc. Models BM06-37, BM06E Series, and BM06S Series; North American Scientific, Inc. Models MED3550, MED3400, and MED3402; Eckert & Ziegler Isotope Products dba Isotope Products Laboratories MED3503, GF Type R Series, RV-XXX Series, and EG-LVM Series)	O. 500 millicuries
P. Any byproduct material permitted by 10 CFR 35.400	P. Sealed Sources (Bard-Brachytherapy, Inc. Model STM 1251; IsoAid, L.L.C. Model IAI-125A; Theragenics Corporation TheraSeed Model 200; North American Scientific, Inc. Models MED3631 and MED3633)	P. 2,000 millicuries
Q. Any byproduct material with atomic numbers 2 through 83	Q. Analytical samples	Q. 50 millicuries
R. Depleted Uranium	R. Metal	R. 400 kilograms

9. Authorized use:

A. through M. Preparation and distribution of radioactive drugs, including compounding of iodine-131, to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for nonmedical use.

F. and G. Redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

N. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.

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O. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.

P. Redistribution for medical use of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution for non-medical use of sealed sources that have been registered either with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess and use the devices.

Q. For possession incident to the performance of leak testing of customers' sealed sources.

R. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1191 S. Brownell Road, Suite 40, Williston, Vermont.

11. Licensed material shall be used by, or under the supervision of:

    A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).

    B. Authorized nuclear pharmacists: Glen Palmer, R.Ph., Richard Sucese, R.Ph., Richard L. Van Sant, R.Ph., Ruth Mary Wetzel, R.Ph., and Zonker White, R.Ph.

    C. Authorized users working under the supervision of an authorized nuclear pharmacist: James Cordonier II, R.Ph., David Ellis, R.Ph., Kevin Hart, R.Ph., Garth Kistner, R.Ph., Peteris Kruze, R.Ph., Laurie Stallings, R.Ph., BCNP, Timothy Summers, R.Ph., Dana Suttle, R.Ph., and Tamiko Ushio, R.Ph.

12. The Radiation Safety Officer for this license is Richard Sucese, R.Ph.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

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B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

D. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

MATERIALS LICENSE SUPPLEMENTARY SHEET

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B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes and vials and their contents.

20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated November 16, 2012 [ML12342A318]
B. Letter dated January 18, 2013 [ML13024A274]
C. Letter dated October 30, 2014 [ML14321A541]
D. Letter dated November 7, 2014

For the U.S. Nuclear Regulatory Commission

Date November 18, 2014

By ***Original signed by Penny Lanzisera***

Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Duplicate

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909-8170

5302 2355017 160929

STATE OF MICHIGAN - DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
REGISTERED PHARMACIST
LICENSE

BYNUM LANIER KIMMONS
3806 ROLLING CREEK CT
BUFORD GA 30519

LICENSE NO. 5302045036
EXPIRATION DATE 06/30/2017
4219919

BYNUM LANIER KIMMONS
3806 ROLLING CREEK CT
BUFORD GA 30519

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENSE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 373-8068

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY

M507302

REGISTERED PHARMACIST

LICENSE

BYNUM LANIER KIMMONS

Tomczak, Tammy

From: Tran, Frank
Sent: Tuesday, October 04, 2016 1:31 PM
To: Tomczak, Tammy
Subject: FW: Amendment Request NRC License 21-32190-01MD
Attachments: VT RAM.PDF; MI amendment.pdf; liscense Michigan.pdf

Hi Tammy,

Please process this request as an amendment.

Thank you, Frank.

From: Richard Van Sant [mailto:rvansant@pharmalogic.info]
Sent: Tuesday, October 04, 2016 12:57 PM
To: Tran, Frank <Frank.Tran@nrc.gov>
Cc: 'Dana Suttle' <dsuttle@pharmalogic.info>; 'Bynum Kimmons' <bkimmons@pharmalogic.info>
Subject: [External_Sender] Amendment Request NRC License 21-32190-01MD

Frank

Please see the attached request to add Bynum Kimmons, RPh as ANP to our MI RAM.

Thank you

Richard L. Van Sant, PharmD
Director Regulatory Affairs
Pharmalogic

7125 Grassmoor Grange Way
Cumming, GA. 30040
Cell: 678.333.5896